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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,540

03/17/2006

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EXAMINER

WESTERBERG, NISSA M

ART UNIT

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1618

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,540	Applicant(s) YOSHINAGA ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 6, 12 - 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 6, 12 - 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed February 19, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 7 – 9 and 11 were rejected under 35 U.S.C. 102(b) as being anticipated by JP 07-048554 (JP'554). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed on November 19, 2007 and those set forth below. Due to the cancellation of claims 7 – 9 and 11, this rejection is now applied to claims 1 and 2.

Applicant argues that the water-in-oil emulsion acrylic pressure sensitive adhesive taught by JP'554 does not meet the newly added claim limitation of a non-aqueous adhesive patch.

This argument is not deemed to be persuasive. The emulsion of the adhesive layer of JP'554 does contain water. However, this water is removed when the adhesive

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layer is dried (see paragraphs [0039] and [0043]). The final adhesive patch composition does not contain water and therefore is a non-aqueous adhesive patch. While the patches exemplified by Applicant in the specification do not contain water at any point, the patentability of a product is not determined by the method by which the product was made (see MPEP 2113).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 4 – 6 were rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2,632,838 (JP'838) in view of JP 08-081331 (JP'331). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed on November 19, 2007 and those set forth below.

Applicant traverses this rejection on the basis that the polymer base composition of JP'838 contains a water absorbing polymer and that sucrose fatty acid ester is not taught by JP'838 as a water absorbing polymer. JP'331 also does not teach sucrose fatty acid ester as a water absorbing material but with a more precise translation of paragraph [0006] that the addition of sucrose fatty acid esters into cosmetics makes cosmetics that excel at absorbing sweat and sebum while not reducing the adherence

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of the cosmetics to the skin. As JP'838 requires a water-absorbing polymer, one skilled in the art would not be motivated to combine these references and that even if an artisan of ordinary skill in the art was motivated, the combination would not result in the claimed invention.

These arguments are deemed not to be persuasive. The water-absorbing polymer in JP'838 is added to absorb sweat and secretions from the skin in order to decrease side effects (p 2 of machine translation of JP'838; p 4 of Dec 2007 translation of '838). JP'331 teaches that sucrose fatty acid esters are also capable of fulfilling this function and do not cause a loss of adhesion to the skin in the cosmetic product containing them. An artisan of ordinary skill would not add the sucrose fatty acid ester to the adhesive patch composition of JP'838 because it was a water-soluble polymer, as Applicant is correct in stating that sucrose fatty acid esters are not a water-soluble polymers, but would rather add the sucrose fatty acid ester to the adhesive patch as an additional ingredient to absorb sweat and secretions to decrease the side effects of the adhesive bandage without a loss of adhesion. Water is not used in the preparation of the adhesive patches of JP'838 and therefore the final patches are non-aqueous.

5. Claims 3 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over JP'554 as applied to claims 1 and 2 above, and further in view of fatty acid definition from Hawley's Condensed Chemical Dictionary, 14th Edition. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed on

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November 19, 2007 and those set forth below. This rejection is now applied to claim 3 due to the cancellation of claim 10.

Applicant traverses this rejection on the basis that sucrose fatty acid ester is not used a water absorbing polymer and the dictionary passage merely exemplifies sugar fatty acid esters.

These arguments are deemed not be persuasive. JP'554 teaches the inclusion of sugar fatty acid ester in the composition and does not require the inclusion of a water absorbing polymer. The presence of the sugar fatty acid ester, regardless of the recognized function of the ingredient in the adhesive patch taught by '554, is sufficient to meet the limitations of the instant claims.

New Claim Rejections - 35 USC § 103

6. Claims 1 – 2, 4 – 6 and 12 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP'838 (all citations from this document are from the translation dated Dec 2007) in view of Chono et al. (US 6,139,866).

JP'838 discloses an adhesive patch which comprises a water absorptive polymer (p 4, paragraph 3). The polymers in the base ingredients used as the adhesive patches include styrene-isoprene-styrene polymers, polyisobutylene polymers (p 6, paragraph 2) and polybutenes (example 4, p 12). A support material (backing) made from a variety of materials can be used with the adhesive patch (p 9, paragraph 5). Any drug may be incorporated into the adhesive base, so long as it is a percutaneous absorbable agent

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(paragraph 2, p 7). Specific compounds exemplified include methyl salicylate, glycol salicylate, 1-menthol, capsicum extract, capsaicin, nonylic acid vanillylamide, ketoprofen and diclofenac sodium (paragraph 2, p 7). The adhesive matrices prepared in JP'838 are non-aqueous as no water is present in the final product as no water is used in the preparation of the adhesive matrix (see the examples, beginning on p 11).

JP'838 does not disclose the inclusion of a sucrose fatty acid ester in the adhesive base.

Chono et al. discloses a tape formulation of fentanyl with low irritative properties to deliver the fentanyl percutaneously (col 1, ln 9 – 17). In the examples, fentanyl is combined with the adhesive ingredients and then applied to a backing material. A transdermal absorption enhancer may be included in the adhesive layer of the adhesive patch (col 4, ln 5 – 6). Among the compounds exemplified as having an enhancing effect on the absorption in skins are sucrose fatty acid esters (col 4, ln 11 – 18).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to add a sucrose fatty acid ester, taught by Chono et al. to enhance transdermal absorption, to the drug containing formulation taught by JP'838 to produce a adhesive patch comprising a sucrose fatty acid ester with enhance delivery of the active agent as both JP'838 and Chono et al. teach drug releasing adhesive patches which comprises the same adhesive base and backing materials.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW